IRB ADVISOR

YOUR PRACTICAL GUIDE TO INSTITUTIONAL REVIEW BOARD MANAGEMENT

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INSIDE

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Consistency is latest buzzword in IRB reviews

Atypical study issues compiled

Protocol review consistency is a hot topic as IRBs, research organizations, and investigators struggle with balancing quality and efficiency in the review process.

Consistency meets both goals, and it prevents complaints of protocols being given the green light at one IRB review, followed up by a similar study being flagged at a later review.

"At IRB meetings, sometimes you'll have [a change in] members, and different people will look at protocols differently," says **Maria J. Arnold**, CIP, IRB clinical research manager at Baptist Health South Florida in Miami.

But most of the time, inconsistency in IRB reviews is the result of investigators giving inaccurate or inconsistent information, Arnold adds.

For instance, an investigator submits a protocol, listing the study personnel who will be providing informed consent. Someone on the IRB staff notices that the list of names is different from the names listed on an ongoing study submitted by the same investigator a few months earlier. If this means the research site has new personnel for its ongoing studies, then the earlier study's change in personnel should have been submitted to the IRB, Arnold explains.

> ...INCONSISTENCY IN IRB REVIEWS IS THE RESULT OF INVESTIGATORS GIVING INACCURATE OR INCONSISTENT INFORMATION.

"This means there has been a change in personnel, and the investigator failed to notify the IRB," she says. "The new study reflects the new personnel, but the older study hasn't been changed to reflect the new people."

These types of inconsistencies could be missed without an IRB pre-review process. *(See story about*

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creating a pre-review process that improves consistency, page 124.)

Historical perspective

Another way to cut down on institutional variation in protocol reviews is to ask investigators to note previous studies that are similar to the current submission, says **Paul Reitemeier**, PhD, chair of the human research review committee and an associate professor of philosophy at Grand Valley State University in Allendale, MI.

According to Reitemeier, IRBs could give investigators instructions that say, "IRB membership changes periodically, and a similar project to one that was reviewed and approved may not be reviewed by the same people. So if this study is similar to a previously reviewed project, please indicate the review number."

Members of an IRB might not recall the last time they reviewed a similar study by a researcher, so asking principal investigators (PIs) for this information can provide historical perspective and improve consistency, Reitemeier says.

Reitemeier and Arnold are scheduled to speak in December about institutional memory and consistency in protocol review at the 2014 Public Responsibility in Medicine & Research (PRIM&R) conference in Baltimore. They are planning to hold an interactive session, presenting four protocol vignettes and asking the audience what they would like to know to make an approval decision, Reitemeier says.

"One of us will write down what people say and we'll put it on an Excel spreadsheet," he explains.

Although it's difficult for an IRB to be consistent when some studies have rare qualities, there is a strategy that will help improve an IRB's institutional memory of how a similar atypical case might have been handled in years past, Reitemeier says.

Keep a separate list of these cases in a spreadsheet, he suggests.

"We have had cases from our own institution that were new and atypical, and we weren't sure how to proceed with our review," he says. "As we stumbled through it, we took lots of notes, and I kept a file."

Over time, the file grew and some of the cases had similarities. This type of file works best as a spreadsheet because it's easier to search for key features and compare notes on the PI, location, kind of review required, which federal agencies are involved, lessons learned, and who the funders are, he adds.

"You can note on the spreadsheet whether there were any other institutions or officers at your institution who you thought should be notified about the study," Reitemeier explains. "These include risk management, legal counsel, and pastoral care."

Case studies

Reitemeier offers two examples of atypical cases:

• **Investigators proposed doing a procedure for which they had no certification.** One example of an atypical case that would make it to the spreadsheet involved a slightly greater than minimal risk exercise study. The PI was a faculty member trained in the United Kingdom and with 20 years of experience in research, including some years in the U.S., Reitemeier says.

"He wanted to draw blood and insert a two-centimeter wire into the muscle to measure temperature, but he was not licensed [for that procedure] in the U.S. or U.K.," he explains. "He had a colleague from Canada who would do the wire insertion."

The dilemma was that the study called for having two non-licensed, non-U.S. individuals perform a procedure that was slightly more than minimal risk.

"They were willing to come under our regulatory oversight and follow U.S. requirements," Reitemeier says.

The IRB checked into what was required for phlebotomy in Michigan and found that it was left to hospitals to provide training. So the IRB asked if any hospitals would train the two investigators or allow them to demonstrate competency for certification. Every single institution said, "No" to this request. They were concerned about legal liability for a non-employee, Reitemeier says.

"Even within our own institution they wouldn't provide training for people for whom they had no oversight," he adds. "It was difficult to get these guys empirically qualified to do what they needed to do for their research."

The study was altered considerably after some weeks of the IRB working with the investigator, he says.

Adding this case to the spreadsheet will help the IRB answer some questions more quickly when similar issues arise, including these:

- What are state regulations for phlebotomy qualifications and training?
- Which departments and offices might have answers to questions about having procedures conducted by legal but non-certified personnel?
- Has risk been minimized in a protocol with an unusual procedure?

• Study involved deception that backfired. Another atypical case involved a student-led project with the goal of assessing agency and government responses to Freedom of Information Act (FOIA) requests. One issue was that the people who would receive the FOIA requests were not going to be told that this was for a research project because investigators wanted to assess compliance, Reitemeier says.

> "WE HAVE HAD CASES FROM OUR OWN INSTITUTION THAT WERE NEW AND ATYPICAL AND WE WEREN'T SURE HOW TO PROCEED..."

"This one didn't work out as well as they hoped because of its timing: It coincided with the first day of spring break, and a lot of schools that were being sent the FOIA had no one available to answer the request," he explains. "The timing caused a burden for them because they were really understaffed."

Another challenge was that FOIA requests often were sent to an attorney who worked with the organization, and sometimes one attorney would handle several different organizations.

When an attorney saw several of the same type of request, he put out a query to other attorneys, saying, "I just got FOIA requests from a number of institutions, and these have the same wording, and I'm not sure what it is."

The researchers had mailed out 350 FOIA requests, and once attorneys began to communicate about the strange requests, they learned that each came from the same source, even pinpointing the university and faculty member involved with it, Reitemeier says.

The IRB learned from this experience that sending out multiple FOIA requests can result in someone tracking the requests back to the investigator. This made the study's attempt to avoid bias a moot point.

"We had anticipated some public relations fallout, but had not contacted our legal counsel about the study, and, in retrospect, we should have done that," Reitemeier says. "We also learned that FOIA requests are holiday-sensitive."

The study had included a statement that asked FOIA recipients to call a specific number if they found the request a burden or if they were going to have difficulty in fulfilling the request. However, it turned out that many recipients had not noticed that sentence, so another lesson learned was that this type of statement should be more prominently placed in the communication, Reitemeier adds.

"We started getting calls from people who were very upset that this FOIA request was a student research project, requiring them to disrupt their work and spring break," Reitemeier says. "So we recognized that the sentence about giving us a call if handling the request would be difficult needed to be highlighted." ■

Pre-IRB review process involves various science, legal experts

Small IRB applies personal touch

Small IRBs often have a resource dilemma: How do you help the IRB improve consistency and quality of reviews when staffing is limited?

One answer would be to have IRB members take on additional work. Few would find that solution practical.

However, one medical center with a small IRB has found success with another strategy: a special pre-IRB review group, called the facilitated review committee, which looks at protocols with the goal of improving consistency and quality. It is supported by the organization's research and grants center, which also provides services in study design, contracts, and coordinators for investigators.

"We have a pre-IRB review process that entails a group of individuals with specific expertise in study design, IRB concerns, contracts, and ethical issues," says **Maria J. Arnold**, CIP, IRB clinical research manager at Baptist Health South Florida in Miami.

Members include Arnold, a compliance administrator, the institution's attorney, a grants and contracts leader, and several researchers.

"We formed the group because we found that each of us had challenges with the review process and having the investigator go back and forth," Arnold says. "We came together and said there had to be a way to facilitate the process and make our jobs and the investigators' jobs simplified."

That's when the organization's Centers for Research and Grants suggested they initiate a facilitated review process prior to the IRB review.

"We're going into our third year, and it has worked very well," Arnold says.

The group's meetings are triggered by protocol submissions. There might be a couple of submissions in one week, or there might be one in several weeks. The committee reviews the application and study documents. When there's a new protocol, the information is sent by email to the pre-review group's members. They have three days to send their comments to the committee chair, who is the supervisor for research at the Center for Research and Grants, Arnold explains.

Committee members can use a simple, one-page minutes checklist that lists the agenda items to be discussed, leaving space for the presenter's name, time, and notes. *(See facilitated review committee tool, page 125.)*

The supervisor forwards comments to investigators, telling them they have four days to address these questions and issues. Once they reply, their answers are forwarded to the committee, and a conference call with the investigator is scheduled. Everyone in the group participates, and any remaining details are ironed out before the investigator's application is forwarded to the IRB for a formal review, she adds.

The pre-review group looks for patterns to ensure consistency.

For example, if several protocols have a similar problem, the group will flag them to take a closer look at what is missing and why.

In another example, an investigator has submitted two similar studies but describes very different consent processes, Arnold says.

"We will ask the investigator why there is a change in the consent process from one study to the next one," she adds.

Committee findings and recommendations are compiled and sent to investigators, who are expected to clarify and address each issue.

Arnold might ask an investigator to clarify why a medical records review will not include informed consent. She also looks at the other committee members' recommendations, gives these to investigators, and asks them to come to the facilitated review committee meeting prepared to answer these questions.

Each pre-review is documented and tracked. "We track all comments and recommendations that are made so that when something comes in for that investigator, it reminds us that we've seen that study," Arnold says. "We look at the concerns raised and whether there is a pattern or a difference in how things are handled."

Investigators learn a great deal from the pre-review process, and the IRB receives submissions that are more complete, she adds.

"We are a small institution *(continued on page 126)*

Baptist Health South Florida

Facilitated Review Committee Minutes

Research Study:			
Facilitators:		**Location: Teleconference**	
Attendees:	See Attendee List	Note taker:	

Topics:

No.	Presenter	Time	Agenda Items
1			• Study Design
2			• Research Operations
3			• Budget/Contract
4			• Informed Consent
5			• Compliance
6			• IRB Concerns

Notes:

No.	Notes
1	
2	
2	
3	
4	
5	
6	

Facilitated Review Committee

with approximately 280 protocols, so this process is beneficial," Arnold says. "We have one-on-one communication with investigators, hold in-services, attend their research meetings, and personally meet with them."

The new pre-review process has resulted in greater consistency and a high approval rate for protocols, Arnold notes.

"A lot of issues have been addressed, and the investigator makes the recommended changes before the IRB review," she says.

"Even though a study goes through this process, it doesn't guarantee that the IRB will approve it," she adds. "This is a mechanism to assist them with the committee and being consistent." ■

IRB workload sharing strategy reduces board member fatigue

Board turnover rate decreases

Research institutions sometimes struggle with retaining experienced IRB members as the workload can be significant and there are so many competing duties and projects for these scientists, professors, bioethicists, and other professionals.

This was a major problem a decade ago at the University of California, Berkeley (UC Berkeley), when two-thirds of the IRB members would leave each year. The most common complaint was, "It's too much work," says **Rebecca Armstrong**, DVM, PhD, director of the research subject protection program.

The high IRB member turnover rate was only part of the problem: Principal investigators levied many complaints in those years, and the IRB process lacked the consistency that Armstrong was certain could be achieved.

What she felt was needed most was a pre-review process, conducted by well-trained and well-educated IRB professionals. This meant changes to the IRB office's staffing level and skills mix.

"I started with the hiring process, advocating for new positions to add to staff to speed up the IRB review turnaround, which was very important to investigators," Armstrong says. "This was a process over a number of years, and it was critical that we hire the right people."

Her strategy was to trust her staff and empower them to conduct IRB pre-reviews.

"We've established a professional workforce and empowered them to make decisions, speaking for the unit, the IRB, and the office," Armstrong adds.

Her goal was to hire people who had advanced degrees, who could become certified, and to provide them with the training and support they would need to succeed. *(See story about maintaining a successful IRB office workforce, page 127.)*

"When a new staff member comes on board, there's a lot of mentoring," says **Tani Prestage**, MA, MPH, CIP, assistant director in the Office for the Protection of Human Subjects at UC Berkeley.

"There are so many nuances to the IRB review process, and issues might not come up every day, but they might come up every few weeks," Prestage says. "So we make sure we're available for a consult with new IRB staff. Once they are past their probationary period, we do weekly staff meetings because we want to make sure there is consistency."

The policy and staff changes have resulted in a number of improvements, including the following:

- IRB members' satisfaction has increased, and now only one or two members leave each year.
- Complaints from investigators have decreased, and when there is a problem, IRB staff are able to resolve these on their own most of the time.
- The IRB submission process now includes a pre-review conducted by very well-trained IRB staff, leading to greater consistency.
- A federal regulatory audit in 2010 had no findings.

"The big end result is, we've reduced the workload for IRB members," Armstrong says. "I think that has a trickle-down effect, enabling us to have stable committee membership."

The pre-review process evolved from a simple checkbox for submission completeness, Armstrong says.

Before the staffing changes, the IRB office was unable to handle analytical work, she notes.

"It has evolved over time, but since 2006, we've had a high-caliber, in-depth, administrative, pre-review process at both expedited and full committee levels," she says.

If an IRB analyst encounters something he or she does not know

how to handle, the analyst will consult with a colleague or contact Prestage for advice.

"Tani is very good at recognizing what kind of issues should be sent to me for interpretation," Armstrong says. "Then we may have a three-way meeting with the staff member, Tani, and me."

These issues are considered in the context of the IRB office's institutional memory of how something similar was handled. If it hasn't been addressed consistently, then a standard operating procedure (SOP) might be written for it, she says.

Once a resolution is found, it might be shared at staff meetings so others can learn from their colleague's experience.

"One of the ways we've developed consistency is through sharing information at staff meetings and making sure we're all on the same page on this," Armstrong says.

Sharing information at staff meetings is a great educational tool, Prestage says.

"Regulations and guidance can be open to interpretation, so different institutions' policies may vary," she says. "This openness provides flexibility, and it is very helpful that we have regular weekly meetings where new UC Berkeley employees can learn different interpretations."

IRB leadership and staff continue to create and revise guidelines and policies.

"Tani and I draft policies that are circulated to staff for review, and then they go to the full committee for policy approval," Armstrong says.

"If a staff member has a particular interest in a subject, then they take the role of drafting guidance and obtaining feedback from their colleagues," she adds. "We get them involved in writing guidelines on how the IRB views these issues."

Principal investigators can use the guidance as they prepare their IRB submissions.

IRB members appreciate the pre-review analyses by the staff, Prestage says.

"At every meeting, there is at least one member who will thank our analyst for giving the board clear comments," she adds. "The board appreciates having that extra reviewer looking at the submission." ■

Success with IRB staffing begins with interview process

Experts share their suggestions

The 21st century IRB office is run by professional-level staff more than in previous years. While 30 years ago an IRB could rely on a long-time employee who had experience without credentials, this model is becoming rare. These days, IRBs increasingly are staffed with people who have bachelor's and master's degrees and human research subjects protection certification.

So how do research administrators find the best-fit employees from the exclusive pool of qualified individuals?

A first step is to advertise the position on both the institution's jobs page and on national IRB forums, such as the PRIM&R job site and IRB Forum, suggests **Rebecca Armstrong**, DVM, PhD, director, research subject protection, University of California, Berkeley.

"We also have advertised locally on Craigslist," she says.

Here are some additional tips on how to hire and retain the best staff for an IRB office:

• Screen applicants personally. "I do all of the screening," Armstrong says. "Human resources doesn't help us screen to see if they're qualified."

Armstrong and her assistant director, **Tani Prestage**, MA, MPH, CIP, look through all of the applications and then select the best qualified applicants for a 30-minute telephone interview.

"I use a set script that I've had for the past 10 years," Armstrong says.

Her telephone interview questions include:

- Why did you apply for this position?
- What did you like most about your previous position?
- What did you like least?
- How do you approach a position that calls for attention to detail?

Armstrong also makes sure candidates are computer literate and asks for examples of how they've multitasked at work, to see if they can multitask successfully.

After the telephone interview, she narrows the candidates down to three to five and has them come into the office for face-to-face interviews.

Additional questions for interviewees might include:

- Describe the three best attributes you have for this position.
- What is your experience in implementing policies and procedures based on regulations?
- Where do you see yourself in five years?

"These are not IRB-specific questions, but they'll give us an idea of their attitude and what their skills are," Armstrong says. "People who are bright — lifelong learners — can learn the regulations and know how to apply them."

The IRB office's staff are included in this next stage. "This helps us identify a group that works well together," Armstrong says.

Armstrong gives staff a template of possible questions, but they can ask what they like. She doesn't sit in on those sessions. Then the final decision is hers.

• New hires are mentored, trained, and empowered. The IRB workload learning curve is high, so mentoring is an essential part of training, Prestage notes.

"We have intensive mentoring," Armstrong says. "It's a coaching model with online training."

New employees are required to take CITI training on both the sociobehavioral and biomedical modules.

"They also take the IRB members' modules so they know what CITI is telling IRB members," Armstrong says.

Since CITI is self-paced learning, they can complete the modules over time.

Each IRB professional is expected to continue education beyond the in-house coaching and mentoring.

"We make a point of sending staff to national meetings and regional meetings," Armstrong says. "This helps them develop confidence and benchmark with other people, learning they are not the only ones with certain issues and problems."

Armstrong has also empowered staff by encouraging them to present topics and papers at PRIM&R.

"This gives them recognition from their peers and lets people know what we do and how we do it," she says. "It's nice for them personally, as well as professionally."

THE IRB WORKLOAD LEARNING CURVE IS HIGH, SO MENTORING IS AN ESSENTIAL PART OF TRAINING..."

• Employees are trained to share the workload. "We share with somebody else so we can cover each other's vacations," Prestage says.

"Or if there's a particularly thorny or urgent issue, they let me know and I watch the protocol for responses," she adds.

At UC Berkeley, employees are placed at various levels of responsibility. The IRB's employees have a range of levels from 2 to 5, depending on their experience and expertise, she adds.

Prestage is at level 5. The committee administrators are level 4s. A new IRB analyst would be a level 2, and everyone else is at level 3. Employees can share the workload within their level or help out with lower levels, she says.

Typically, each employee is assigned a protocol panel that stays with him or her for the duration of the study. This way employees know it very well, and it makes for a more efficient process. But sometimes an IRB employee is out of work, and this requires someone else to look at that project.

"One reason it's easy for people to cover their colleagues' workload is because we have an all-electronic IRB approval system," Armstrong says. "We can go into anyone's panel and reassign protocols."

If someone is out of work for an extended period of time, then work assignments are shifted electronically.

• Earn staff's trust through giving them yours. "I really back up the staff," Armstrong says.

When an investigator complains or refuses to do something the IRB office asked, then Armstrong backs up her employee's decision.

"We work so hard on consistency and make sure the staff has the right knowledge, that I am able to back them up," she explains. "I let principal investigators know that the information they received from my staff is correct."

On the rare occasion that the PI was given the wrong information, Armstrong will admit it — viewing the situation as a teachable moment — but most of the time she can confirm what the IRB employee said.

Over time, PIs learned that they could not obtain a different result by complaining to IRB leadership, so the complaints dwindled down to far fewer each year, Armstrong says. ■

Experts share strategies for COI management

Education, communication are key

The 2011 changes to the National Institutes of Health (NIH) Public Health Service (PHS) regulations for reporting investigator conflicts of interest may still be causing confusion for researchers and IRBs.

The NIH COI rules lowered the significant financial interest from $10,000 to $5,000, received in the previous 12 months. The interests can include stock options from a pharmaceutical company, speaking fees, etc. But the 12 months was not defined as a calendar year, leaving IRBs to determine the 12-month window at their discretion.

"That raises a lot of questions in terms of when the disclosure information changes, and when it's appropriate to remove it [the conflict disclosure] from the informed consent," says **Rebecca Flores Stella**, CIP, manager of IRB operations and education at Cedars-Sinai Medical Center Office of Research Compliance and Quality Improvement in Los Angeles. "It's important for the institution to define when the 12-month window is starting."

COI management plans

Not all IRBs follow the NIH's $5,000 threshold. "Some institutions have a zero-dollar threshold," says **Julie Blasingim**, MBA, CIP, board chair at Schulman Associates IRB in Cincinnati and Ft. Lauderdale. "We have found the $5,000 threshold to be sufficient for subject safety, and always have the option to request a management plan for financial conflicts that are lower than $5,000."

If an investigator discloses a significant financial interest, management plans are created by the investigator or the IRB to minimize the conflict's effect on the study. "Supplemental forms for additional information [on the conflict] are geared toward understanding what the conflict is and how the investigator plans to manage it," Blasingim says. "What we have found is oftentimes the investigators are looking to the IRB to provide their expertise on ways they can manage the conflict, particularly for investigator-initiated studies."

> THE NIH COI RULES LOWERED THE SIGNIFICANT FINANCIAL INTEREST FROM $10,000 TO $5,000, RECEIVED IN THE PREVIOUS 12 MONTHS.

Usually, Schulman IRB requires the investigator to notify study participants of the conflict in the informed consent process and forms, Blasingim says. "It's rare that we would not have such disclosure in the informed consent," she says. "The disclosure could include how much stock the person has [in the sponsor company]. If a person has substantial ownership in the company, we might say that they could be on the research team but not be involved in the consent process." If there is a possibility that the conflicted person could bias the study data, he or she may be asked not to be involved with the data analysis. "An independent monitor may be requested as an added safeguard for certain types of conflicts," she adds.

Cedars-Sinai has an algorithm to determine the conflicted investigator's participation in a study, taking into account the size of the study and the number of sites involved, among other criteria. "We could limit the conflicted investigator's participation in the recruitment and consent processes, and/or could restrict their ability to be the one who signs off on eligibility of final subjects," Flores Stella says. "We could also restrict them from participating in the research intervention, depending on the study design. We haven't restricted investigators from participation in data analysis because findings would likely undergo scientific merit consideration when submitted to peer-reviewed journals."

Management tips

IRB professionals offer these tips for managing investigator COI:

• **Mandatory education for researchers and investigators on institutional and NIH requirements.** Unclear institutional criteria can lead to unintentional non-disclosure of COI information, particularly when rules differ

between IRBs. For instance, an investigator who has worked with IRBs using the $5,000 NIH COI threshold may go to an IRB with a zero-dollar threshold. If he or she is unaware of the different threshold, it could lead to noncompliance issues. "If investigators are used to working with Schulman and go to someone else with a zero-dollar threshold, [non-disclosure] is an honest mistake," Blasingim says. "In the IRB world, there needs to be consistency and clarity provided to investigators so they know what to expect and what type of information to submit."

• **Have an algorithm in place for consistent management plans.** Not all conflicts are the same in terms of severity or effect on the study. Some conflicts may only require a disclosure on informed consent documents, while others may mean the investigator should take on a smaller role in the study. Having sets of criteria to determine the extent of COI can aid in management plan consistency. "Build an algorithm to look at particular circumstances to help guide decisions and determine whether the person can make impartial decisions for the study," Flores Stella says.

Creating an algorithm can be complicated if everyone on the IRB is not on the same page. Hold in-depth discussions to get everyone in agreement, Flores Stella says. "It's something that all institutions struggle with because it's a judgment call," she says. "Some believe that any level of financial interest affects impartiality, and others believe the financial interest has to be very significant to have that kind of impact on the decision-making and integrity of the study. That's a tough question for anyone to deal with."

Institutions must also consider what constitutes a conflict, and what may be payment received for product education or development. "One of the hardest things to track in this is when someone is paid legitimately to do a study,"

> "IN THE IRB WORLD, THERE NEEDS TO BE CONSISTENCY AND CLARITY PROVIDED TO INVESTIGATORS SO THEY KNOW WHAT TO EXPECT..."

says **Susan Rose**, PhD, executive director for the office for the protection of human subjects at the University of Southern California in Los Angeles. "If they do it [a study], they have to get money. But if they do a speaking tour or advisory committee, we want to know how a pharmaceutical company is paying for their speech — through the education department or through marketing. Paying for education is different from paying for marketing. The costs of doing the study are not conflict of interest costs; they're the costs of doing business."

• **Have a solid system in place for COI reporting.** Electronic IRB systems help ensure that COI information is up to date, and that information doesn't fall through the cracks. "In the prior system there were challenges getting information across, but the new electronic system helps to cross-check everyone and that's been very helpful," Flores Stella says.

It's also less likely that a study would get underway before a conflict is discovered, Rose says. "It's so rare that a study gets so far [without disclosure] because there are such good filters to check it before a study gets approved," she says.

When USC's disclosure system indicates that there's a financial COI, the study can't go forward until the university's conflict of interest committee reviews it. "They have to make a decision before the study gets approved," Rose says. "Sometimes it happens

COMING IN FUTURE MONTHS

- Ethical challenges in the age of Big Data
- New SACHRP members reveal goals
- Common Rule changes revisited
- Considering vulnerable populations in research

the other way and a disclosure is made on the annual review form. The system stops the approval until the committee says it's OK; then the IRB can approve."

Conflict of interest committees are also important tools for COI management, Blasingim says. "We have a conflict of interest committee, and it's a great way of having experts in the areas of COI, including legal representatives, to evaluate each conflict of interest and their management plan," she says. "They can monitor the submissions that come in from the investigator to make sure we're getting accurate information."

• **Keep communication open and constant with multisite research.** If the central IRB criteria don't match your institution's criteria, work together to ensure that both sets of requirements are met, Blasingim says. "A lot of investigators will send submissions to central IRBs, and also be required to have their own internal or local COI committees assess and clear the conflict before they can proceed with a central IRB," she says. "When we serve as the local IRB, we work closely with those groups. Communication and clarity up-front are key to ensuring conflicts are appropriately disclosed and managed for human subject protection." ■

Send us your thoughts

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CNE/CME QUESTIONS

1. Inconsistency in IRB reviews is caused by which of the following, says Maria J. Arnold, CIP?

A. An IRB's membership has changed since a similar study was approved, and the new board finds issues that were not flagged previously
B. Investigators give inaccurate or inconsistent information from one protocol submission to the next
C. Both A & B
D. None of the above

2. According to UC Berkeley IRB, before an IRB office can handle in-depth, analytical, pre-review work, what is a chief change that might be necessary?

A. The IRB will need one or more researchers on staff
B. The IRB will need well-educated, certified, highly-trained staff
C. The IRB will need a chair that is highly trained on the administrative side of research
D. All of the above

3. Which of the following is an excellent question to ask interviewees for a position in the IRB office, says Rebecca Armstrong, DVM, PhD?

A. Would you please describe the three best attributes you have for this position?
B. What is your experience in implementing policies and procedures based on regulations?
C. Where do you see yourself in five years?
D. All of the above

4. According to Susan Rose, PhD, a pharmaceutical company payment to an investigator may not be a conflict if it is for which of the following?

A. A promotional tour
B. Paid for through the education department
C. Paid for through the marketing department
D. Used for a promotional speech

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